



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Northeast Region

State Programs Branch
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Telephone: 617-279-1675 x147

June 20, 1995

Mr. Harold C. Winters
Director
Bureau of Marine Development
State House, Station 21
Augusta, ME 04333

Dear Mr. ^{Winters}Winters:

Enclosed is the trip report which describes the findings of the evaluation of the growing area survey and classification portion of the Maine Shellfish Sanitation Program. The items found which do not meet the satisfactory compliance requirements of the National Shellfish Sanitation Program are identified on the worksheets for each growing area. They have been extracted and tabulated by area on the trip report attachment Summary of Cited Deficiencies by Area.

In accordance with the FDA Molluscan Shellfish Compliance Program (FOCUS '95), you are advised that the Category 2 and Category 4 deficiencies were found as noted on the Summary of Cited Deficiencies by Area.

The finding of a Category 2 deficiency initiates the Unresolved Issue process of the ISSC. You are afforded 30 calendar days from the date of this letter to respond to this office. FDA will advise you in writing within 30 calendar days of your written response if it is acceptable and resolves the deficiencies. If you do not respond, your response is found to be unacceptable, or if you disagree with the trip report findings, FDA will notify the Commissioner of the Department of Marine Resources that FDA considers the matter to be an Unresolved Issue.

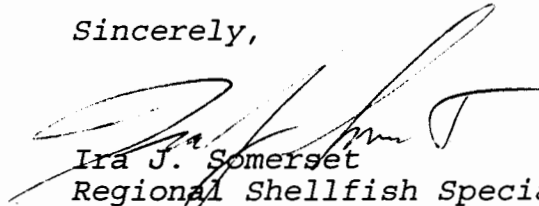
The finding of a Category 4 deficiency requires that you submit an action plan to this office within 30 calendar days detailing how and when you will achieve compliance, and how you will demonstrate that you have achieved compliance. Corrections should be made as soon as possible.

Deficiencies not corrected by the action plan will be treated as Category 2 deficiencies.

Within 30 calendar days of your written response, FDA will advise you in writing if your action plan is acceptable to resolve the deficiencies. If you do not respond, your response is found the unacceptable, or if you disagree with the trip report findings, FDA will then treat the deficiency as a Category 2 deficiency for Unresolved Issue action by the Interstate Shellfish Sanitation Conference.

The Category B deficiencies should be addressed in the process of correcting the Category 2 and Category 4 deficiencies. Please do not hesitate to contact me if you have any questions.

Sincerely,



Ira J. Somerset
Regional Shellfish Specialist

Enclosure - Trip Report

pc: Field, HFR-NE24
SPIB, HFR-628 w/enclosure
Brands, HFC-152 w/enclosure
P. Anderson w/enclosure✓



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date June 20, 1995
From Regional Shellfish Specialist
Northeast Region
Subject Trip Report
To Maine Files - Focus '95

I. Purpose and Time Period

A review of the growing area survey and classification program element was conducted between May 17 and May 18. This evaluation was conducted in accordance with the protocol and procedures of Focus '95.

II. Scope

There are 45 designated growing areas in Maine, of which 17 are to be evaluated under the Focus '95 process. This part of the program evaluation took place at the Lamoine Laboratory which is responsible for the eastern half of the state. Eight areas were reviewed.

III. Persons Contacted

Lamoine Laboratory: Paul Anderson

IV. Findings

Copies of the worksheets are attached, as is a compilation by growing area of cited deficiencies. There were 12 Category 2 deficiencies, 2 Category 4 deficiencies, and 8 B-category deficiencies.

V. State Action

During the evaluations, there was discussion of each deficiency and why it did not meet the requirements. Mr. Anderson took notes and discussed means to effect corrections and bring the program into compliance with the Focus '95 criteria. A partial response was received in June, 1995.

VI. State Accomplishments

The program staff continues to cope with the effects of the severe budget restrictions imposed on the state employees: reduced work week (to 37.5 hours); state shut-down days (5/year); and unpaid time off.

There has been a considerable amount of work expended by the Lamoine Lab staff to address the deficiencies noted in the Focus '94 evaluation and to develop procedures to assure that they were not repeated. To that end, several quality control procedures and checks, report formats and operating procedures have been developed and instituted.

In addition, the Bureau of Industry Services reorganization has been approved by all levels of government in Maine and will be effective October 1, 1995. The revised structure will place the regional biologists under Walter Foster; and the plant sanitation, growing area survey and classification, and the laboratories under Paul Anderson.

In response to the Focus '94 recommendations, the following actions have been taken:

1. Resurveys of all areas have been scheduled so they can be completed in timeframes that preclude conducting a triennial reevaluation followed by a complete resurvey.
2. Standard reporting and evaluation procedures and methods have been developed and are being refined. Regional training courses are being held four times a year to train approximately 80 volunteers (past experience indicates that about 10-20 percent will stay with the program).
3. Required corrections of complex deficiencies with no immediate adverse classification implications will be accomplished through current and future survey work. Any new classifications or upgrades will be consistent with the current requirements (new shoreline survey, new data analysis, new sanitary survey).
4. The designation of type of source (direct/indirect) is being done.
5. The Lamoine Lab staff are working on methodology to determine rainfall effects (preferably by computer).
6. The conditionally approved portions of area EL are being resurveyed.

VII. Recommendations

The recommendations were discussed with program managers:

- A. Continue the progress made addressing previous and current deficiencies.
- B. Continue resurveying and updating surveys as scheduled.
- C. Continue to review the existing sanitary surveys to assure that they meet the requirements of the NSSP to justify the classification assigned to the area and present a comprehensive and persuasive argument that the classification is correct.

Ira J. Somerset

Attachments (Worksheets, Summary)

Summary of Cited Deficiencies by Area

<u>Area</u>	<u>Nonconformity</u>	<u>Enforcement Category</u>
X	None	
EA	C.4.d.iv(b) (vi)	B
	C.4.d.iv(b) (v)	4
	C.4.d.iv(b) (vii)	2
ED	None	
EF	C.1.d.ii	2
	C.6.d.iv(a)	2
	C.6.d.iv(b) (vi)	B
	C.b.d.iv(b) (v)	4
	C.b.d.iv(b) (vii)	2
EH	Appendix B question 4	2
	Appendix B question 5	B
	Appendix B question 7a, 7b	B
	C.1.d.ii	2
EL	Appendix B question 5	B
	Appendix B question 7a, 7b	B
	C.1.d.ii	2
	C.4.d.iii(a)	2
	C.4.a. question 1	2
	C.4.d.iv(b) (vi)	B
	C.3.c.ii	2
EP	C.1.c.	2
	C.1.d.ii	2
ES	Appendix B question 7a, 7b	B

Trip Report - Maine Molluscan Shellfish
Sanitation Program Review

I. Purpose and Time Period

The purpose of this trip was to conduct an evaluation of a portion of the Maine Molluscan Shellfish Plant Sanitation Program. The basis for this review was the FDA Molluscan Shellfish Evaluation Compliance Program (Focus '95). The file work was conducted by Ira Somerset, FDA/Northeast Region on October 18, 25, and 26, 1995.

II. Scope

The Focus '95 process identified a total of seventeen shellfish growing areas to be reviewed: eight in Lamoine and nine in Boothbay Harbor. The eight Lamoine areas were the subject of a June 20, 1995 trip report. The areas reviewed at this time were:

- Area A - Piscataqua River
- Area F - Fortunes Rocks
- Area G - Saco Bay
- Area I - Casco Bay
- Area M - Kennebec River
- Area Q - Damariscotta River
- Area S - Mosconus Bay
- Area T - Meduncook River
- Area V - Spruce Head

Copies of all pertinent documents are attached.

III. Persons Contacted

Arrangements for this inspection were made with Mr. Paul Anderson. A closeout meeting was held with Mr. Anderson on October 26, 1995.

IV. Findings

In conducting the inspections, it was evident that there has been improvement in the general level of compliance in the content and format of the sanitary surveys, annual and triennial reevaluations. However, more consistency in the survey and classification procedures is necessary for the program to be more effective. The specific observations are noted on the area worksheets, and are summarized in Attachment 1.

Attached are the forms for the file review of the areas.

Category 2A deficiencies initiate the Unresolved Issue process, Category 4A deficiencies require the development of an acceptable action plan document, and all other observations require a general response detailing what corrective actions will be taken and the timeframes. There were twenty seven Category 2A deficiencies, five Category 4A deficiencies, and three other deficiencies noted in the file review.

V. State Actions

Following the review last year, significant changes were made, which were reflected in many of the documents reviewed. In the closeout discussion, Mr. Anderson said that he planned to work with the surveyors in the Boothbay Lab, and to promote more uniformity and pattern the approach to report writing after the system used in the Lamoine Lab. These changes will begin as soon as possible after the reorganization.

VI. State Accomplishments

In reviewing the files, improvements were noted in some of the sanitary survey, annual and triennial reports.

VII. Recommendations

Given the personnel situation at the time of writing this report and the planned reassignment of program responsibilities and authority, it is recommended that the planned changes in philosophy and methodology be implemented as soon as possible.

Summary of Findings

Area A - Piscataqua River	
Minimum number of samples not obtained	2A
Management plan does not meet requirements	2A
C/A openings not in accordance with management plan	2A
No annual evaluation of C/A management plan in field (4A) or in writing (2A)	2A, 4A
Did not collect 30 samples at each station	2A
Area F - Fortunes Rock	
2 of 3 stations did not have 30 samples	2A
Insufficient sample data	2A
Area G - Sacco Bay	
Appendix A information missing	4A
Area I - Casco Bay	
Appendix K information missing	4A
No annual evaluation of conditional areas	2A
Not all stations have 30 samples/station	2A
Marina policy misapplied	4A
Area M - Kennebec River	
Survey information scattered and presentation confusing	B
No shoreline survey report	2A
Potential discharges and drainage ditches not evaluated	B
Pollution sources not labelled as direct/indirect	B
No shoreline survey prepared	2A
No analysis of sanitary survey data	2A
Report did not determine if classification is appropriate	2A
Statements in annual update indicate 3 areas did not meet approved area criteria when open	2A
No triennial evaluation	2A
Area not closed because of lack of triennial reevaluation	2A
No written conditional area management plan	2A
No annual review of conditional area	2A
No annual field evaluation of pollution sources	4A
Area Q - Damariscotta River	
NSSP guidelines may not have been applied correctly to classify this area	2A
Conditionally approved area not adequately reevaluated annually	2A
Conditionally restricted area has no written	2A

management plan in file	
Insufficient samples collected at some stations	2A
Area S - Muscongus Bay	
No triennial evaluation	2A
Area T - Meduncook River	
Data does not support rainfall conditional classification	2A
Insufficient samples	2A
Water quality standards not met in conditionally approved area	2A
Area V - Spruce Head	
Opening around island based on mainland sample stations. Stations subsequently located at islands had less than 30 samples/station	2A